APPROVING SUN CARE INGREDIENTS: WHAT MUST BE DONE?


It's not just for Australians anymore!

The state of sunscreen regulations is in flux. The US Food and Drug Administration (FDA) recently signaled its intention to regulate future sunscreens in the US differently. Dr. Joshua Sharfstein, former FDA deputy, wrote an article in the New England Journal of Medicine entitled "A Spotlight on Sunscreen Regulation."[1] This article was endorsed by Dr. Robert Califf, the nominee to replace Dr. Margaret Hamburg as the new chief of the FDA. His nomination is now pending in Congress.

Dr. Sharfstein's article summarizes the state of sunscreen regulations in the US. He acknowledges that the FDA has rejected the eight new European sunscreen ingredients currently pending for the last 12 years for inclusion as UV actives under the Time and Extent Application (TEA). This was decided by the FDA despite the recent passage of The Sunscreen Innovation Act (SIA) in Congress—unanimously—and signed by President Obama into law in November 2014. He argues that the SIA did not fully consider the agency's framework for review of sunscreens, the resources needed and the public health role.

I plan to first analyze the FDA's critical view of approving new sunscreen actives in the US, as this article and the many statements made by the agency and its representatives have a number of very important messages that are obvious, but also may contain potentially subliminal messages signaling the role the FDA intends to pursue in regulating sunscreens in the future. I will then conclude with my own observations on where the FDA is heading with regulations and also the role that the industry and supporters should play to effect real change in future regulations of sunscreens manufactured in the USA.

Slip, Slop, Slap, Seek and Slide

Unlike the US, Australia has succeeded in reducing skin cancer incidents among the younger population. Australia, with a population that is predominantly light skinned, lies in one of the most vulnerable locations in the world in terms of excessive ultraviolet and infrared rays from the sun. The nation pursues very aggressive measures to protect its population with public service reminders of slip on a shirt, slop on sunscreen, slap on a hat, seek shade and slide on sunglasses.[2] In the face of the epidemic of skin cancer incidents in the US[3] and the US Surgeon General's call to action to prevent skin cancer,[4] it behooves the powers-that-be to advocate similar messages and protection for our populous.

In his article, Dr. Sharfstein acknowledges that existing sunscreen regulations in the US are not, even now, the subject of a final regulation by the FDA. Unlike the review for new prescription drugs, he cites the pathway for over-the-counter (OTC) products is supported by inadequate resources and procedural requirements that resulted in regulations which proceed in slow motion as compared to the rest of the agency. In the article he stresses the need for more resources over five times! In rejecting the eight TEA ingredients for use in the US, he cites that their approval allows companies to manufacture a broad array of formulations and dosages that can be marketed extensively. This, he argues, would prevent the FDA from its ability to require the collection of data on long-term safety or efficacy. He adds

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that even if new troubling safety information on these OTC products comes to light, the FDA cannot alter its approach quickly to ban these products. These limitations, he declares, would understandably lead to a cautious approach to approving products, such as sunscreens, that are designed for long-term use by millions of healthy children and adults.

Class(ification) Acts

The FDA's approach, as a result of all the preceding arguments, is that sunscreens are classified as drugs. Suppliers and sunscreen manufacturers should seek a New Drug Application (NDA) if they wish to add a new ingredient into the sunscreen monograph. This is the approach that Herbert Laboratories took in the 1980s to get Avobenzone approved and also, more recently, L'Oréal to approve Ecamsule in the US. Avobenzone was finally listed as a Category I ingredient in 1996, but Ecamsule remains captive to one formulation approved exclusively for L'Oréal. Ecamsule is one of the eight ingredients that aspire to receive a blanket approval through the TEA process.

To approve TEA ingredients, the FDA recently signaled that these ingredients have to conform to GRASE (Generally Recognized As Safe and Effective) requirements. These requirements are more stringent than obtaining an NDA! To approve a GRASE ingredient for long term consumer use, extensive testing is required, including prolonged exposure data such as long-term skin irritation studies, carcinogenicity, teratogenicity, mutagenicity and developmental toxicology required for each UV filter.

The FDA recently signaled, however, that it will accept the results of the Maximum Use Trial (MUsT) test. This 30-day test was developed by the FDA to evaluate the potential for systemic drug absorption at the upper limit of use covered by the clinical trials and allowed for in the label. The MUsT trial must demonstrate a de minimus rate of absorption of no greater than 0.5 ng/ml. It should be pointed out that the MUsT test has never been tested on any sunscreen ingredient and the threshold limit suggested is arbitrarily set. Two additional and very telling statements were made by Dr. Sharfstein. The first is that "the Federal Government should consider whether it makes sense to continue allowing products to be marketed as sunscreen without evidence of protection against skin cancer."[1] This, in my opinion, is a statement reflecting FDA's reluctance to support drug claims (e.g. that sunscreens protect against skin cancer) for products that have an SPF less than 15 or do not have a broad spectrum claim. I believe that these claims that sunscreen use may protect the consumer from skin cancer bolster the FDA's classification of sunscreens as drugs rather than special cosmetics.

The second is Dr. Sharfstein's view that Congress should try again to pass legislation establishing an alternative approval pathway that combines the flexibility of the new drug pathway with the ability to simultaneously approve multiple formulations and concentrations (as in all cosmetics). That is the first subtle hint I see from the FDA that perhaps, in the future, it may entertain reclassifying sunscreens from drugs to special cosmetics.

Four Points

I have followed the regulation process in the US since its inception in 1978 starting with the Advanced Notice for Public Record (ANPR) to its current status in 2015 (more than 37 years), and I have reached the following conclusions that have been reinforced by listening carefully to the FDA during this long tedious process of finalizing regulations:

1. The process to finalize the Final Monograph remains remote and lengthy, possibly extending to 2019 as cited in one of the provisions of the SIA.

2. The process for approving the TEA ingredients is tedious but the current glimmer of hope from the FDA shows that the Administration would be willing to review results of the MUsT test. This process will not be easy since the test is novel with no precedents in sunscreens. Too many variables need to be ironed-out before the MUsT test is a valid pathway to approval.

3. Skin cancer in the US will continue to grow unabated due to the fact that few, if any, of the old habits of over exposure to the sun have been avoided or better measures for protection have been strictly observed. People are not avoiding the sun. To date, consumers (especially younger adults) are being exposed to UVA radiation in tanning salons; people are still frequenting the beaches and sun locations without proper protection of hats, clothing, umbrellas and most of all, spreading adequate amounts of effective sunscreens all over their bodies. US sunscreens are simply not the best and lack the proper ingredients for UVA I (340-400nm) protection. In addition, protection from infrared (IRA) rays is not readily available in today's consumer products.

From sunscreen to hats to sunglasses, the message in Australia is to use many levels of sun protection. But most Americans don't abide.

4. Finally, the lack of superior sun care products in the US is crippling the industry's efforts to adequately protect the consumer. As the statistics clearly show, innovation in the US is seriously lagging behind Europe, Brazil, Japan and China. The last approved UV filter in the US was Avobenzone, in the 1980s, (Ecamsule was approved more recently but is captive to L'Oréal exclusively.)

A Sad State of Status Quo

In conclusion, it is my belief that this sad state of affairs in sunscreen consumer protection will remain the same for quite a while until the premise of regulating sunscreens as drugs is changed. It is high time that we begin the process of changing the regulatory process of sunscreens in the US from regarding them as drugs to special cosmetics requiring pre-approval and registration.

Except for Canada, Australia and the US, sunscreens are regulated as cosmetics in most of the world. Already Canada allows sunscreens regulated in Europe as cosmetics, to be used, and Australia has created a new category of sunscreen cosmetics. The US is still adamant in regulating sunscreens only as OTC drugs. The US sun care industry simply cannot compete on the world stage with the limitations currently imposed.

Drugs are supposed to "treat" and "protect" disease. Sunscreens, in my opinion however, are similar to prophylactics (to prevent venereal disease by using condoms) or body armor (to prevent soldiers from being injured from bullets) or seat belts (to prevent car accident injuries). Sunscreens simply prevent ultraviolet or infrared radiation from penetrating the skin. They are not "protecting" the skin from the cancer by interacting with DNA material in the body nor are they "treating" any skin or biological condition.

Properly formulated sunscreens especially those that conform to the 500 Dalton Rule, contain appropriately designed ultraviolet filters that do not penetrate the skin. Rather, they are designed to only reflect or absorb the harmful radiation on the surface of the skin prior to interacting with our skin components in the epidermis, dermis or beyond. They simply do not qualify as drugs.

The conversation is underway but we await resolution. This process of discussing the merits of reclassifying sunscreens as special cosmetics instead of OTC drugs has begun in earnest during the Florida Sunscreen Symposium. I also understand that discussions on the topic were debated at the Personal Care Product Council. In the future the Public Acess to SunScreens (PASS) coalition will debate this too. A healthy exchange of ideas is imperative for movement towards change. With the confirmation of Dr. Robert Califf as the new FDA commissioner, it is my hope and belief that a new page in regulating sunscreen products in the US may begin. ●

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